K141233

Medtronic

JUN 12 2014

510(k) Summary

Date Prepared: May 9, 2014

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Jessica Sixberry
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Device Name and Classification:

Trade Name:	Affinity Pixie® Cardiotomy Venous Reservoir with Carmeda® BioActive Surface or with Balance® Biosurface
Common Name:	Cardiotomy Venous Reservoir
Classification Name:	Blood Reservoir, cardiopulmonary bypass
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.4400, 21 CFR 870.4270, 21 CFR 870.4230
Product Code:	DTN, JOD, DTP
Classification:	Class II

Predicate Devices

Medtronic Affinity Pixie® Cardiotomy Venous Reservoir with Carmeda® BioActive Surface or with Balance® Biosurface (K100645)

Device Description

The Medtronic Affinity Pixie Cardiotomy Venous Reservoir (CVR) is a single use device designed to collect and store blood during extracorporeal circulation. Cardiotomy blood is collected, filtered, and defoamed before mixing with the filtered venous blood. The reservoir can also be used for vacuum-assisted venous drainage.
The Affinity Pixie Cardiotomy Venous Reservoir is coated with either Carmeda BioActive Surface or Balance Biosurface. The device is single-use, nontoxic, nonpyrogenic, and supplied sterile for clinical use.

Models	Description
BBP241	Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir Balance Biosurface

Alleviating Pain · Restoring Health · Extending Life

Models	Description
CBP241	Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir Carmeda BioActive Surface

Indications for Use

The Affinity Pixie Cardiotomy/Venous Reservoir with Carmeda BioActive Surface or Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Cardiotomy/Venous Reservoir is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

Comparison to Predicate Devices

The Affinity Pixie CVR has the same intended use, design and materials, and principles of operation and technology when compared to the predicate Affinity Pixie CVR.

- Intended Use: The intended use is the same as the predicate device.
- Design: The design is the same as the predicate device.
- Materials: The materials of the Affinity Pixie CVR are the same with the exception of the protective port caps which have undergone a minor formulation change.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance of the device is the same as the predicate device.

Summary of Performance Data

Bench testing was used to verify the performance characteristics of this device. Clinical testing was not required to establish substantial equivalence.

The following performance tests were conducted:

- Biocompatibility
- Cap removal force
- Cap particulate generation

Conclusion

Medtronic has demonstrated that the Affinity Pixie CVR is substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Medtronic, Inc.
Ms. Jessica Sixberry
Principal Regulatory Affairs Specialist
7611 Northland Dr.
Minneapolis, MN 55428

Re: K141233
Trade/Device Name: Affinity Pixie Oxygenation System with Carmeda BioActive Surface or Balance BioSurface
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II
Product Code: DTN, JOD, DTP
Dated: May 9, 2014
Received: May 13, 2014

Dear Ms. Sixberry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K141233

Device Name: Affinity Pixie Oxygenator System with Carmeda Bioactive Surface or with Balance Biosurface

Indications for Use:

ModelBBP241:

The Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Carmeda BioActive Surface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The Affinity Pixie Cardiotomy/Venous Reservoir is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

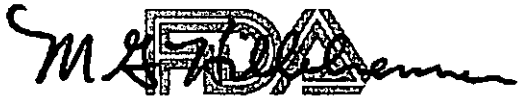
See next page for Model CBP241.

Prescription Use _X_ OR Over-The-Counter Use ____

Per 21 CFR 801.109

(PLEASEDONOTWRITEBELOWTHISLINE-CONTINUEONANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Model CBP241:

The Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.
The Affinity Pixie Cardiotomy/Venous Reservoir is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.